

IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE

IN RE:

AREDIA[®] AND ZOMETA[®] PRODUCTS
LIABILITY LITIGATION

(MDL No. 1760)

This Document Relates To Case Nos.:

3:06-cv-00371 (*Bartoli*)

3:08-cv-00923 (*M. Brown*)

3:06-cv-00387 (*Burt*)

3:06-cv-00372 (*Cartelli*)

3:06-cv-00386 (*Carter*)

3:06-cv-00505 (*Conklin*)

3:08-cv-00213 (*Earp*)

3:06-cv-00957 (*Georges*)

3:06-cv-00385 (*Grizzle*)

3:06-cv-00373 (*Guilbeau*)

3:06-cv-00812 (*Harvey*)

3:06-cv-00374(*Hendrix*)

3:06-cv-00862 (*C. Hill*)

3:06-cv-01126 (*Humes*)

3:06-cv-00394 (*Ingram*)

3:06-cv-00772 (*Jenkins*)

3:06-cv-00369 (*L. Johnson*)

3:06-cv-00504 (*Joslin*)

3:06-cv-00370 (*Knopf*)

3:06-cv-00527 (*McKay*)

3:08-cv-00216 (*Messick*)

3:08-cv-00918 (*Newman*)

3:06-cv-00382 (*Perkins*)

3:06-cv-00742 (*Porter*)

3:06-cv-00384 (*Radin*)

3:06-cv-00383 (*H. Shrum*)

3:06-cv-01059 (*Stambolian*)

3:06-cv-00771 (*Thorn*)

3:06-cv-00390 (*Wallace*)

No. 3:06-MD-1760

JUDGE CAMPBELL

MAGISTRATE JUDGE BROWN

NOVARTIS PHARMACEUTICALS CORPORATION'S *DAUBERT* MOTION
TO EXCLUDE TESTIMONY OF PLAINTIFFS' EXPERTS DR. ROBERT
FLETCHER, DR. KEITH SKUBITZ, DR. JAMES VOGEL, PROFESSOR WAYNE RAY,
DR. SUZANNE PARISIAN, AND DR. ROBERT MARX

On February 22, 2011, plaintiffs designated Drs. Robert Fletcher, Keith Skubitz, James Vogel, Suzanne Parisian, and Robert Marx and Professor Wayne Ray as expert witnesses to testify regarding general issues across all of the “Wave II” cases. *See* Letter from Charles Patrick Flynn to Katharine R. Latimer (Feb. 22, 2011) (Ex. 1). In keeping with this Court’s deadlines for *Daubert* motions and pursuant to Fed. R. Civ. P. 10(c), Novartis Pharmaceuticals Corporation (“NPC”) adopts by reference the entirety of the *Daubert* motions, memoranda in support, and all exhibits it filed on June 1, 2009 in the “Wave I-A” cases, as well as the later supplements to those motions filed on July 31, 2010 in the “Wave I-B” cases and October 14, 2010 in the “Wave I-C” cases, and seeks to exclude the testimony of these witnesses on those and the following grounds.

I. Dr. Suzanne Parisian

NPC moved to exclude Dr. Parisian’s testimony in Wave I-A. *See Daubert Mot. to Exclude Test. of Pls.’ Expert Dr. Parisian*, ECF No. 2280; *Mem. in Support of Daubert Mot. to Exclude Test. of Pls.’ Expert Dr. Parisian*, ECF No. 2282. On August 13, 2009, the Court declared NPC’s *Daubert* motion moot. Order, ECF No. 2816. On December 7, 2010, this Court declared a similar motion, ECF No. 3420, filed in the Wave I-B cases moot. Order, ECF No. 4040. In Wave I-C, ECF No. 3781, NPC supplemented its motion to describe the exclusion of Dr. Parisian’s testimony in another case involving a pharmaceutical product; that motion was not decided prior to remands.

NPC submits and adopts (by reference) its prior motions to preserve its *Daubert* challenges before the trial courts on those matters that this Court may deem moot in the event that summary judgment is not granted and to preserve its right to challenge on appeal any ruling allowing the testimony of Dr. Parisian.

If this Court decides to examine the admissibility of Dr. Parisian's opinions, it should be aware that in a recent decision in a remanded Wave I-A case, a federal court precluded Dr. Parisian from testifying, finding that her testimony did not survive scrutiny under *Daubert* or Rule 702 on the same grounds as asserted in NPC's prior motions in this Court. In *Hogan v. Novartis Pharmaceuticals Corp.*, No. 06 Civ. 0260 (BMC)(RER), --F. Supp. 2d --, 2011 WL 1533467 (E.D.N.Y. Apr. 24, 2011), Judge Cogan made clear his "concern that all of plaintiff's experts, to some degree, are being proffered as 'superlawyers' to serve as scientifically informed advocates of conclusions that plaintiff wants the jury to reach and which belong only in summation, not expert testimony." *Hogan*, 2011 WL 1533467, at *5 (Ex. 2).

Judge Cogan excluded Dr. Parisian's proposed testimony in its entirety, finding that portions did not "fit" plaintiff's case. For example, Judge Cogan considered Dr. Parisian's proffered testimony, as set forth in her 120-page expert report and her deposition testimony, as being that of a "regulatory expert to opine on regulatory and labeling issues . . . to testify on these issues under federal law," *Hogan*, 2011 WL 1533467, at *1, and noted that it was "[u]nclear under this articulation of the case is where Dr. Suzanne Parisian's testimony fits," *id.*

Judge Cogan also held that Dr. Parisian was not qualified to testify on the topic of pharmacovigilance – a pharmaceutical company's actions in monitoring the safety of a drug once it has come onto the market. *Hogan*, 2011 WL 1533467, at *3. Regarding her experience, Judge Cogan noted that Dr. Parisian had neither worked for a pharmaceutical company nor the branch of the FDA that regulates drugs (she worked in the medical devices branch). *Id.* at 6. "Given this background," the court held, "I find that she is unqualified to opine on the potentially relevant testimony she offers in her report regarding pharmaceutical companies' internal

operating procedures and other standards with which she claims manufacturers voluntarily elect to comply.” *Id.* at 3.

In the *Deutsch v. Novartis Pharmaceuticals Corp.* (another remanded former Wave I-A case), the Court excluded Dr. Parisian’s testimony regarding what a “reasonable manufacturer would do” and “industry standards” given her lack of qualifications. *See Order, Deutsch v. Novartis Pharms. Corp.*, No. 09-CV-4677 (ADS)(WSW), -- F. Supp. 2d --, 2011 WL 790702, at *46 (E.D.N.Y. Mar. 8, 2011) (Ex. 3) (internal quotation omitted). The *Deutsch* court held a 2-day *Daubert* hearing on the other of Dr. Parisian’s opinions, and NPC’s motion to exclude those opinions is pending.

II. Dr. Robert Marx

NPC moved to exclude Dr. Marx’s testimony in wave I-A. *See Novartis Pharms. Corp.’s Daubert Mot. to Exclude Litigation-Wide Test. of Pls.’ Expert Dr. Robert Marx, D.D.S., ECF No. 2379*; *Novartis Pharms. Corp.’s Mem. in Support of Daubert Motion to Exclude Litigation-Wide Test. of Pls.’ Expert Robert Marx, D.D.S., ECF No. 2383*. On August 13, 2009, the Court denied NPC’s *Daubert* motion in part and declared it moot in part. *Order, ECF No. 2814*. On December 7, 2010, this Court declared a similar motion, *ECF No. 3418*, filed in the Wave I-B cases moot. *Order, ECF 4037*. A similar motion filed in Wave I-C, *ECF No. 3899*, was not decided prior to remand.

NPC submits and adopts (by reference) its prior motions to preserve its rights to file *Daubert* challenges before the trial courts on those matters that the Court may deem moot in the event that summary judgment is not granted and to preserve its right to challenge on appeal any ruling allowing Dr. Marx’s testimony.

If this Court decides to examine this issue, it should be aware that in the same decision in which he excluded Dr. Parisian's testimony in its entirety, Judge Cogan in the *Hogan* matter excluded Dr. Marx's opinions that certain NPC conduct constituted "bad faith." *Hogan*, 2011 WL 1533467, at *4. He also held that with regard to alleged corporate admissions that clinical trial patients had ONJ, "[i]t is unclear why Dr. Marx should be the one to present [that evidence]." *Id.* at *6. Judge Cogan also barred Dr. Marx from offering criticisms of NPC's design of its clinical trials. *Id.* at *6. In a later Order, Judge Cogan held that Dr. Marx, like plaintiffs' other witnesses, will not "be permitted to read emails and other documents that the jury can interpret itself; evidence that did not form the basis of reliable expert opinion will not form the basis of expert testimony in Court." *Hogan v. Novartis Pharms. Corp.*, No. 06 Civ. 0260 (BMC)(RER), Order 2 (E.D.N.Y. May 3, 2011) (Ex. 4).

The court in another remanded Wave I-A case also recently granted in part NPC's *Daubert* motion and precluded Dr. Marx from commenting on whether NPC acted in good faith or otherwise testifying about the company's intent or motivations. *Deutsch*, 2011 WL 790702, at *26 ("To the extent that Dr. Marx seeks to offer the legal conclusion that Novartis acted in bad faith . . . that testimony is impermissible . . . It is for the jury to decide whether Dr. Marx's experiences imply that Novartis was acting in bad faith."). NPC seeks to exclude the same opinions and testimony here.

III. Dr. Robert Fletcher

NPC moved to exclude Dr. Fletcher's testimony in wave I-A. *See Daubert* Mot. to Exclude Test. of Pls.' Expert Dr. Robert Fletcher, ECF No. 2305; Mem. in Support of *Daubert* Mot. to Exclude Test. of Pls.' Expert Dr. Robert Fletcher, ECF No. 2307. On August 13, 2009, the Court declared NPC's *Daubert* motion moot. Order, ECF No. 2817. On December 7, 2010,

this Court declared a similar motion, ECF No. 3423, filed in the Wave I-B cases moot. Order, ECF No. 4039. A similar motion filed in Wave I-C, ECF No. 3782, which described the exclusion of Dr. Fletcher's testimony in another case regarding the same medications and alleged injuries at issue in the Wave II cases, was not decided prior to remand.

NPC submits this motion and incorporates (by reference) its prior motions to preserve its right to file *Daubert* challenges before the trial courts on those matters that this Court may deem moot in the event that summary judgment is not granted and to preserve its right to challenge on appeal any ruling allowing this witness' testimony.

If this Court decides to address NPC's motions, it should be noted that two courts in this litigation have already considered NPC's *Daubert*/Rule 702 challenges and excluded his testimony in its entirety. *See, e.g., Deutsch*, 2011 WL 790702, at *41; *Bessemer v. Novartis Pharms. Corp.*, No. MID-L-1835-08, Order Granting Def. NPC's Mot. to Exclude Test. of Dr. Robert Fletcher (N.J. Super. Ct. Apr. 30, 2010) (Ex. 5). These courts found Dr. Fletcher's testimony irrelevant, and the *Deutsch* court, the only federal court to adjudicate this issue, concluded that the proffered opinions were not an appropriate subject for expert testimony. *Deutsch*, 2011 WL 790792, at *39. The same result should follow here.

IV. Wayne Ray, Ph.D.

NPC moved to exclude Professor Ray's testimony in Wave I-A. *See Daubert* Mot. to Exclude Test. of Pls.' Expert Wayne Ray, Ph.D., ECF No. 2384; Mem. in Support of *Daubert* Mot. to Exclude Test. of Pls.' Expert Wayne Ray, Ph.D., ECF No. 2386. On August 13, 2009, the Court declared NPC's *Daubert* motion moot. Order, ECF No. 2812. On December 7, 2010, this Court declared a similar motion, ECF No. 3419, filed in the Wave I-B cases moot. Order,

ECF No. 4038. A similar motion filed in Wave I-C, ECF No. 3784, was not decided prior to remand.

NPC submits and adopts (by reference) its prior motions to preserve its rights to file *Daubert* challenges before the trial courts on those matters that the Court may deem moot in the event that summary judgment is not granted and to preserve its right to challenge on appeal any ruling allowing Professor Ray's testimony.

If this Court addresses the merits of NPC's motion, it should be noted that in a remanded former Wave I-A case, another federal court recently excluded portions of Professor Ray's testimony based on his improper methodology. *See Deutsch*, 2011 WL 790702, at *35 (finding that Professor Ray failed to employ a reliable methodology with respect to his Table 6 meta-analysis). Dr. Ray's methodology is similarly faulty in his pending report here.

V. Dr. Keith Skubitz

NPC moved to exclude Dr. Skubitz' testimony in Wave I-A. *See Daubert* Mot. to Exclude Test. of Pls.' Expert Dr. Keith Skubitz, ECF No. 2288; Mem. in Support of *Daubert* Mot. to Exclude Test. of Pls.' Expert Dr. Keith Skubitz, ECF No. 2290. On August 13, 2009, the Court denied NPC's *Daubert* motion in part and declared it moot in part. Order, ECF No. 2810. On December 7, 2010, this Court declared a similar motion, ECF No. 3421, filed in the Wave I-B cases moot. Order, ECF No. 4034. A similar motion filed in Wave I-C, ECF No. 3784, was not decided prior to remand.

NPC submits and adopts (by reference) its prior motions to preserve its rights to file *Daubert* challenges before the trial courts on those matters that this Court may deem moot in the event that summary judgment is not granted and to preserve its right to challenge on appeal any ruling allowing Dr. Skubitz's testimony.

VI. Dr. James Vogel

NPC moved to exclude Dr. Vogel's testimony in wave I-A. *See Daubert* Mot. to Exclude Test. of Pls.' Expert Dr. James Vogel, ECF No. 2359; Mem. in Support of *Daubert* Mot. to Exclude Test. of Plfs.' Expert Dr. James Vogel, ECF No. 2367. On August 13, 2009, the Court denied NPC's *Daubert* motion in part and declared it moot in part. Order, ECF No. 2811. On December 7, 2010, this Court declared a similar motion, ECF No. 3424, filed in the Wave I-B cases moot. Order, ECF No. 4036. A similar motion filed in Wave I-C, ECF No. 3783, was not decided prior to remand.

NPC submits and adopts (by reference) its prior motions to preserve its rights to file *Daubert* challenges before the trial courts on those matters that this Court may deem moot in the event that summary judgment is not granted and to preserve its right to challenge on appeal any ruling allowing Dr. Vogel's testimony.

May 19, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have on this 19th day of May 2011 served a true and correct copy of the foregoing Novartis Pharmaceuticals Corporation's *Daubert* Motion to Exclude Testimony of Plaintiffs' Experts Drs. Robert Fletcher, Keith Skubitz, James Vogel, Suzanne Parisian, and Robert Marx and Professor Wayne Ray by operation of the Court's Electronic Case Filing System, on Plaintiffs' Liaison Counsel:

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